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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,616	02/27/2002	Chihiro Uematsu	NITT.0065	1757

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EXAMINER

HORLICK, KENNETH R

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 06/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/083,616

Applicant(s)

UEMATSU ET AL.

Examiner

Kenneth R Horlick

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8 and 9 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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1. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. It is suggested that "regarding adenylation" be added to the current title.

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 9 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. This claim is drawn to a "service", which does not fall under any of the statutory categories of invention as set forth above.

3. Claims 1, 3, and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 1 and dependent claim 3 are confusing because the sequence "GC" is recited, which is in conflict with the specification, which recites the importance of the sequence "GG" rather than "GC" (see also claim 2). Correction/clarification is required.

B.) Given that claim 9 is drawn to a "service", as well as recites some method-type steps comprising passive language, the metes and bounds clearly cannot be determined.

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4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by either of Nevalainen et al. (US 5,834,286) or Guerinot et al. (US 6,162,900).

These claims are drawn to: a primer comprising a first sequence complementary to a target, and a second sequence located in the 5'-direction relative to said first sequence, said second sequence having at the 5'-terminus a GA or GG (GC in the claim appears to be a typographical error; see above) which is non-complementary to the target; and drawn to a method of amplification using such a primer.

Nevalainen et al. disclose 2 primers, UPPHOS and DOWNPHOS, which have a first sequence complementary to a target gene, and at the 5'-end a non-complementary sequence which appends a restriction site to the amplification product, and begins with the sequence GA (see column 30, lines 40-54), and use of the primers in PCR amplification. With respect to claim 5, it is noted that the Taq DNA polymerase typically used in PCR reactions has terminal transferase activity, and that detection of amplified DNA by electrophoresis is taught also.

Guerinot et al. disclose "Primer 1", which has a first sequence complementary to a target gene, and at the 5'-end a non-complementary sequence which appends a restriction site to the amplification product, and begins with the sequence GG (see column 38, lines 5-16), and use of the primer in PCR amplification.

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These disclosed primers and methods of use thereof satisfy the claim language.

5. Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by Smith et al. (US 6,110,710).

This claim is drawn to a method comprising: providing four types of primers which have non-complementary sequences at the 5'-ends and complementary sequences at the 3'-ends, wherein the base at the 5'-end is different in the four types of primers; carrying out PCR using said four types of primers; analyzing the results of the PCR to obtain adenylation efficiencies; and deciding which non-complementary sequence is most likely to undergo adenylation.

Smith et al. disclose such a method in Fig. 1 and columns 7-8. It is noted that the first four primers with added tails in Fig. 1 comprise tails which are identical except for the 5'-terminal base, which is different among them.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Nevalainen et al. (US 5,834,286) or Guerinot et al. (US 6,162,900).

Claim 3 is drawn to the primer as described and rejected above, wherein the base length of the first sequence is 12 to 20. Claim 4 is drawn to the method as described and rejected above, wherein the second primer, or both the first and second primers, are fluorescence labeled.

In the references, the disclosed primers have a first sequence which is 21 or 22 bases long, slightly outside the range specified in the claim. Further, the primers are not labeled with fluorescence markers.

One of ordinary skill in the art would have been motivated to shorten the primers of either of Nevalainen et al. or Guerinot et al. by one or two bases because, as would have been well understood in the art, doing so would have produced primers only trivially different and clearly expected to have the same specificity/function. One of ordinary skill in the art would have been motivated to use fluorescent labels in either or both of the primers of Nevalainen et al. or Guerinot et al. because such labels in primers and probes was conventional in the art to facilitate detection; a well-known advantage of fluorescent labels is the avoidance of the dangers of radioactive labels. It would have

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been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make the claimed primer, and to carry out the claimed method.

7. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al.

These claims are drawn to a method similar to claim 6 as described and rejected above, further comprising preliminarily preparing a primer as indicated in the method, and checking whether or not the primer has a stable secondary structure.

Smith et al. do not disclose such a checking step.

One of ordinary skill in the art would have been motivated to check the primers of Smith et al. for stable secondary structure because, as is indisputable, it was well known and common knowledge in the art at the time of the invention that such secondary structure was undesirable in primers as leading to deleterious results in PCR amplification. Indeed, the instant specification recites on page 26, "...base sequences of a PCR forward and a PCR reverse primer...are so designed according to a conventional method as to have an appropriate T_m value and not to form either an interprimer or intraprimer secondary structure" (emphasis added). Thus, this statement can be taken as an admission that this additional step of checking for secondary structure follows straightforward reasoning and does not contribute to patentability. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

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8. Claim 7 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Further to the method of claim 6 wherein four primers are tested to determine the best base at the 5'-end position, claim 7 requires testing four additional primers having a fixed 5'-end position to determine the best base at the next base in from the 5'-end. While Smith et al. investigate the base positions 2, 3, and 4 from the 5'-end of primers to some extent, it can be seen in Smith et al. Fig. 1 that this is not done in the systematic manner of instant claim 7. For example, in the set of primers in said Fig. 1, only C and T are represented in the second position from the 5'-end.

9. No claims are allowable.

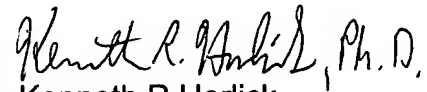
10. Haff (US 2003/0039976) is made of record as a reference of interest.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 703-308-3905. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-0294 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Kenneth R Horlick
Primary Examiner
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June 24, 2003